#### <u>REMARKS</u>

#### I. Formal Matters

## A. <u>Restriction/Rejoinder</u>

The Office indicates that method claims 45-49 will be rejoined if the product claims are found allowable and the method claims are commensurate in scope with the allowed claims and do not raise any issues under 35 U.S.C. § 112, first paragraph. (Office Action at paragraph 1A.) Applicants thank the Office for this indication, and request that method claims 50-54, added to the application in the Amendment filed April 7, 2003, be treated in a similar manner.

With regard to claims 50-54, Applicant notes that these claims were filed in response to a request by the Examiner that claim 45 be separated into two claims, one directed to a method for assaying a ligand of a heptahelix receptor, and the other directed to a method for assaying antagonists and agonists of a ligand of a heptahelix receptor. See the Amendment of April 7, 2003.

# B. <u>Status Of Amendments</u>

The Office states that the Office Action was issued in response to Applicant's

Amendment filed February 19, 2003. (Office Action at paragraph 1B.) Applicant respectfully submits that an Amendment was also filed on April 7, 2003. Because many of the issues raised in the Office Action were addressed in the Amendment of April 7, 2003, Applicant is attaching, as Appendix A, a copy of that Amendment (along with a copy of a stamped postcard indicating receipt of the Amendment by the Office on April 7, 2003) to ensure that the PTO file is accurate.

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP

# II. Declaration Regarding Sequencing Errors

The Office states that a new Declaration be submitted, confirming that the Lyme21-9 clone originally disclosed in the application was the same clone that both Dr. Owman and Dr. Bristulf sequenced. (Office Action at paragraph 2A.) A Declaration addressing the Office's concern was submitted on April 7, 2003. A copy of that Declaration is attached as part of Appendix A. Accordingly, Applicant requests that the Office reconsider and withdraw the requirement for a new Declaration.

## III. Claim Objections

### A. <u>Claims 40 and 41</u>

The Office objects to claims 40 and 41 as substantial duplicates of claims 38 and 39, respectively. (Office Action at paragraph 3A.) Claims 40 and 41 were cancelled in the Amendment filed April 7, 2003. Accordingly, Applicants request that the Office withdraw this objection.

#### B. <u>Claim 44</u>

The Office objects to claim 44, asserting that a recombinant protein comprising the sequence of SEQ ID NO:2 would be the same protein as a non-recombinant one. (Office Action at paragraph 3B.) Applicants respectfully traverse this objection and submit that, although the primary amino acid sequence of proteins produced by both methods would be the same, the proteins themselves could be different. For example, as disclosed on page 20, lines 1-2 of the present specification, it is possible that CMKRL1 proteins produced recombinantly in microbial systems could have different glycosylation patterns than those produced as wild-type proteins

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP

expressed from the genome of cells in which they are normally expressed. For at least this reason, Applicant submits that a recombinantly produced CMKRL1 protein could differ from a non-recombinantly produced CMKRL1 protein, even though the two would have the same primary amino acid sequence. In view of the different scopes of protection provided by claims 44 and 16, Applicant requests that the Office reconsider and withdraw the objection to claim 44.

# IV. Rejection Under 35 U.S.C. § 112, first paragraph

The Office rejects claims 38 and 40 under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description. (Office Action at paragraph 4A.) More specifically, the Office states that a Declaration under 37 C.F.R. § 1.804 must be submitted. In the Amendment of April 7, 2003, claim 40 was cancelled and a Declaration Under 37 C.F.R. § 1.804 was submitted. See Appendix A. Applicant submits that the Declaration filed April 7, 2003, satisfies the requirement of 37 C.F.R. § 1.804. Accordingly, Applicant requests that the Office reconsider and withdraw the rejection of claim 38 under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description.

# V. Rejections Under 35 U.S.C. § 102

## A. Yokomizo et al.

The Office rejects claims 16 and 38-44 under 35 U.S.C. § 102(a) as anticipated by Yokomizo *et al.* (Office Action at paragraph 5A.) Applicant respectfully requests reconsideration and withdrawal of the rejection in view of the attached Declaration of Dr. Owman.

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

Attached to this response as Appendix B is a Declaration Under 37 C.F.R. § 1.131 of Dr. Christer Owman, the applicant and inventor. The Declaration states that Dr. Owman was in possession of clone Lyme21-9, which encodes the full-length CMKRL1 protein, before the publication date of Yokomizo *et al.* Because Dr. Owman was in possession of the Lyme21-9 clone, and thus the CMKRL1 protein, before the publication date of Yokomizo *et al.*, Yokomizo *et al.* does not qualify as prior art against the present application. Thus, regardless of whether or not Yokomizo *et al.* discloses a protein that is identical or similar to the presently claimed protein, Yokomizo *et al.* cannot be used to reject the present claims. Accordingly, Applicant respectfully requests that the Office reconsider and withdraw the rejection of claims 16 and 38-44 as anticipated by Yokomizo *et al.* 

## B. Akbar et al.

The Office rejects claims 16 and 38-44 under 35 U.S.C. § 102(b) as anticipated by Akbar et al. (Office Action at paragraph 5B.) In rejecting the claims, the Office asserts that Akbar et al. discloses a protein that has an amino acid sequence that is 100% identical to present SEQ ID NO:2. Applicant respectfully disagrees.

Attached to this response as Appendix C is a comparison of the amino acid sequences of Akbar et al. ("Akbar") and present SEQ ID NO:2 ("Owman"). In the comparison, identical amino acids between the two sequences are indicated by a vertical line connecting the two.

Amino acids that differ are not connected by a vertical line. As can be seen from the comparison, the amino acid sequences of Akbar and Owman differ at two amino acid residues. These

Fax 202.408.4400

www.finnegan.com

FINNEGAN HENDERSON

FARABOW

A comparison with "Raport" is also included, and will be discussed below.

GARRETT &
DUNNER LLP

1300 | Street, NW
Washington, DC 20005
202.408.4000

residues are at positions 272 (Akbar discloses Valine, whereas Owman discloses Alanine) and 293 (Akbar discloses Valine, whereas Owman discloses Leucine). In view of the differences between these two sequences, the protein disclosed by Akbar *et al.* does not anticipate and of the present claims.

For at least this reason, Applicant requests that the Office reconsider and withdraw the rejection of claims 16 and 38-44 under 35 U.S.C. § 102(b) as anticipated by Akbar *et al.* 

## C. Raport et al.

The Office rejects claims 16 and 38-44 under 35 U.S.C. § 102(b) as anticipated by Raport et al. (Office Action at paragraph 5C.) In rejecting the claims, the Office asserts that Raport et al. discloses a protein that has an amino acid sequence that is 100% identical to present SEQ ID NO:2. Applicant respectfully disagrees.

As noted above, attached to this response as Appendix C is a comparison of the amino acid sequences of Raport *et al.* ("Raport") and present SEQ ID NO:2 ("Owman"). In the comparison, identical amino acids between the two sequences are indicated by a vertical line connecting the two. Amino acids that differ are not connected by a vertical line. As can be seen from the comparison, the amino acid sequences of Raport and Owman differ at one amino acid residue - position 246 in Owman's sequence and position 271 in Raport's sequence. In view of the difference between these two sequences, the protein disclosed by Raport *et al.* does not anticipate any of the present claims.

For at least this reason, Applicant requests that the Office reconsider and withdraw the rejection of claims 16 and 38-44 under 35 U.S.C. § 102(b) as anticipated by Raport *et al.* 

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP

## VI. Conclusion

Applicant respectfully submits that this application is in condition for allowance. Therefore, Applicant respectfully requests that the Office reconsider and withdraw the outstanding objections and rejections, rejoin method claims 45-54, and allow this application to issue as a U.S. patent in due course.

If the Office believes anything further is necessary in order to place this application in condition for allowance, Applicant requests that his undersigned representative be contacted at the telephone number or e-mail address listed below.

Please grant any extensions of time required to enter this response, and charge any required fees that are not submitted herewith to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Bv:

Matthew T. Latimer Reg. No. 44,204

571-203-2714

matthew.latimer@finnegan.com

Date: September 15, 2003

Attachments:

Appendices A-C

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP